In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-1750V

MONIQUE COOMBES, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 24, 2024

Laura Levenberg, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Parisa Tabassian, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING[1]

On August 24, 2021, Monique Coombes filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") resulting from an influenza ("flu") vaccine received on October 23, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find that record evidence preponderantly establishes that Petitioner suffered the residual effects of her injury for more than six months.

I. Relevant Procedural History

After the case was activated, Petitioner was directed to file worker's compensation records and additional evidence demonstrating that the statutory severity requirement had been met (ECF No. 11). Petitioner thereafter filed additional evidence (ECF Nos. 13, 16, 22, 24). Efforts to settle the claim thereafter were unsuccessful.

On July 12, 2023, Respondent filed his Rule 4(c) Report and motion to dismiss (ECF No. 33). Respondent argued that the claim should be dismissed due to a failure to meet the severity requirement, and added that he "reserve[d] analysis of petitioner's Table claim and any potential future Causation-in-Fact claim, unless and until petitioner cures the aforementioned statutory severity defect." *Id*. at 13 n.7. During a telephonic status conference, there was discussion about whether Respondent's Report complied with Vaccine Rule 4(c), which requires Respondent's Report to fully set forth his position (ECF No. 34). Respondent was offered the opportunity to amend his Report, but declined to do so unless ordered otherwise. *Id*. Petitioner reacted to Respondent's dismissal request on October 24, 2023 (ECF No. 35).

II. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his or her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

In addition to requirements concerning the vaccination received and the lack of other award or settlement,[3] a petitioner must establish that he or she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he or she received. Section 11(c)(1)(C). The Vaccine Act further includes a "severity requirement," pursuant to which a petitioner demonstrate that they:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

"[T]he fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury." *Morine v. Sec'y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); *see also Herren v. Sec'y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) ("a discharge from medical care does not necessarily indicate there are no residual effects"). "A treatment gap . . . does not automatically mean severity cannot be established." *Law v. Sec'y of Health & Human Servs*., No. 21-0699V, 2023 WL 2641502, at *5 (Fed. Cl. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where petitioner sought care for under three months and had met physical therapy goals but still lacked full range of motion and experienced difficulty with certain activities, then returned to care nearly five months later reporting stiffness and continuing restrictions in motion); *see also Peeples v. Sec'y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. Cl. Spec. Mstr. May

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception and has not filed a civil suit or collected an award or settlement for his or her injury. Section 11(c)(1)(A)(B)(E).

26, 2022) (finding severity requirement met where the petitioner sought care for four months, followed by fifteen month gap); *Silvestri v. Sec'y of Health & Human Servs*., No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity requirement satisfied where petitioner did not seek additional treatment after the five month mark.

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g*. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

III. Relevant Factual History

This ruling contains only a brief overview of facts most relevant to the parties' dispute.

A. Medical Records

On October 23, 2019, Petitioner received a flu vaccine in her left deltoid. Ex. 1 at 1. She saw her neurologist 12 days later for "severe intractable headaches," but without mentioning any problems with her shoulder. Ex. 6 at 95.

Nearly a month after vaccination (November 19, 2019), Petitioner saw physician assistant ("PA") Kelly Beach. Ex. 2 at 27. Petitioner complained of left shoulder pain for three weeks that she believed was due to her vaccination three weeks earlier having been administered too close to the shoulder joint. *Id*. She had been having pain with movement since then. *Id*. On examination, Petitioner's left shoulder range of motion ("ROM") was limited due to pain, and she had "moderate to marked tenderness" over the lateral aspect of her left shoulder joint. *Id*. at 28. PA Beach assessed her with acute pain of the left shoulder and provided naproxen and an urgent referral to a sports medicine clinic. *Id*.

Three days later (November 22, 2019), Petitioner saw orthopedist Dr. Kelly Wilkinson. Ex. 2 at 22. Petitioner reported left shoulder pain that began in late October after her flu vaccination. *Id*. She had felt a burning pain while the vaccine was injected that had since progressed, and her shoulder hurt with movement and ached at night. *Id*. On examination, she was tender to palpation over the lateral shoulder, with full ROM and positive results on the Hawkins impingement test. *Id*. at 23. Dr. Wilkinson diagnosed Petitioner with bursitis of the left shoulder and administered a subacromial steroid injection. *Id*. If Petitioner did not improve, Dr. Wilkinson planned to order physical therapy ("PT") and/or imaging such as an ultrasound or MRI. *Id*.

The following month (December 16, 2019), Petitioner saw Dr. April Dillion to follow up on her left shoulder pain and other health concerns. Ex. 2 at 19. The steroid injection had helped, but her shoulder was still painful. *Id*. Petitioner's shoulder was not examined at this visit. Two days later, Petitioner called Dr. Wilkinson's office, stating that the

cortisone injection helped "a bit" but she was still in pain and her arm was "not normal." *Id*. at 75. A follow up was scheduled for January 2020, and PT and an MRI were ordered.

Petitioner saw Dr. Wilkinson on January 9, 2020. Ex. 2 at 13. On examination, she continued to have tenderness to palpation over the lateral shoulder. *Id*. at 14. Her ROM and strength continued to be normal, and she again had positive results on the Hawkins impingement test. *Id*. She was assessed with bursitis and given rotator cuff exercises. *Id*.

Petitioner saw her neurologist later that month (January 27, 2020) for migraine treatment, without mentioning her shoulder pain. Ex. 6 at 77. On February 27, 2020, Foothills Physical Therapy sent a fax to Dr. Wilkinson stating that they had tried to contact Petitioner and had been unable to schedule an evaluation for her. Ex. 2 at 163. Petitioner saw her neurologist for migraine treatment on April 22 and July 15, 2020, without mentioning her shoulder problems. Ex. 6 at 55, 66. Thus, by mid-summer 2020, Petitioner had not received direct treatment for her alleged shoulder injury for over six months.

Two months later, on September 15, 2020, Petitioner returned to Dr. Wilkinson. Ex. 2 at 7. She reported some improvement with the November 2019 steroid injection done in November 2019 and home exercises, but complained that "the pain has worsened over the past several months." *Id*. It now hurt with any movements, and she had difficulty doing her home exercises. *Id*. She had not had an MRI. *Id*.

On examination, she had normal ROM and reduced strength, with positive results on the Hawkins impingement test and "vague" positive result son the drop arm test. Ex. 2 at 8. A diagnostic ultrasound was suggestive of rotator cuff tendinosis, with diffuse thinning of the supraspinatus, infraspinatus, and subscapularis tendons and small areas of full thickness tearing. *Id*. Dr. Wilkinson discussed treatment options including a repeat steroid injection, PT, an MRI, or a surgical referral. *Id*. Petitioner elected to proceed with a surgical referral, which Dr. Wilkinson thought was reasonable given her minimal improvement with a prior injection and potential difficulty doing PT exercises. *Id*.

Eight days later (September 23, 2020), Petitioner saw orthopedist Dr. Jennifer Miller for left shoulder pain that had started in October 2019 after a flu vaccination. Ex. 3 at 16. Petitioner stated that the vaccine was administered too high on her shoulder, and she now had pain with abduction, forward flexion, horizontal adduction, reaching behind, and radicular symptoms down to her elbow. *Id*. At worst, the pain was ten out of ten in intensity. *Id*. On examination, her ROM in forward flexion had a painful arc starting at 80 degrees, and her external rotation was 20 degrees. *Id*. at 18. She had reduced strength and positive results on the Hawkins and Neer impingement tests as well as the O'Brien's and Speed's tests. *Id*. X-rays were normal, and a diagnostic ultrasound confirmed a supraspinatus tear that appeared to be incomplete. *Id*. at 19. Her subscapularis and infraspinatus tendons were normal, and there was no obvious biceps pathology. *Id*. Dr. Miller discussed treatment options, and Petitioner elected to proceed with arthroscopic rotator cuff repair. *Id*. at 20. Dr. Miller prescribed Norco for pain relief. *Id*.

Six days after her consult with Dr. Miller (September 29, 2020), Petitioner underwent left shoulder manipulation under anesthesia, left shoulder arthroscopy with subacromial decompression and acromioplasty, debridement of calcific deposit in the supraspinatus tendon, and arthroscopic repair of the supraspinatus tendon. Ex. 3 at 7. While under anesthesia, Dr. Miller took Petitioner's shoulder through ROM and found it to be "significantly tighter" than anticipated. *Id*. at 7-8. Dr. Miller had assumed that some of Petitioner's loss of motion was due to pain, but found a "firm endpoint" with forward flexion of about 150 degrees. *Id*. at 8. While performing a manipulation under anesthesia, Dr. Miller heard "audible tearing" as she restored Petitioner's forward flexion to 180 degrees. *Id*. A shoulder immobilizer was placed, and Petitioner was to start PT to work on ROM due to the adhesive capsulitis identified during surgery. *Id*. at 9.

After her surgery, Petitioner continued seeking care for her shoulder injury with a variety of modalities until July 2022.

B. Worker's Compensation Records

Petitioner filed a worker's compensation claim for her vaccine-related injury on November 21, 2019. Ex. 10 at 86. On January 3, 2020, additional evidence on her diagnosis was requested. *Id*. at 78. She was advised of deficiencies in her claim on March 6, 2020 and given the opportunity to file additional evidence. *Id*. at 60. She filed additional evidence five days later. *Id*. at 57, 61. Her claim was denied on April 10, 2020 because "the evidence does not establish that you were injured in the performance of duty."[4] *Id*. at 53. It was determined that even though her injury occurred at a workplace health fair, participation in the fair (and thus the vaccination received in connection with it) was not required by her job. *Id*. at 54.

C. Declarations

Petitioner filed two declarations in support of her claim. Exs. 5, 8. She states that the gap in care from January to September 2020 "was initially due to the confusion with workers comp and being told that I couldn't seek treatment until they had approved me." Ex. 8 at ¶ 4. Worker's compensation eventually denied her claim because, although she received the flu vaccine at work and the vaccine was encouraged, it was not required. *Id*. at ¶¶ 5, 6.

Her orthopedist gave her a cortisone injection and exercises to do at home, so she "was doing the treatment that was prescribed to me the best I could." Ex. 8 at ¶ 8. The COVID-19 Pandemic was also going on during this time, and "we were scared, and being told that unless something was life threatening we should all be staying home, which is

[4] The record indicates that her worker's compensation claim was reopened and "accepted" on June 21, 2022 due to further review supporting that she was injured in the performance of her duties. Ex. 10 at 38. Petitioner should file any updated worker's compensation records.

what I did with my family." *Id*. at ¶ 9. She eventually sought treatment again in September because she "realized that covid wasn't going anywhere" and because she "could hardly use my left arm and definitely couldn't stand the pain anymore [she] felt [she] had to take the risk with covid to seek help once again." *Id*. at ¶ 10.

IV. The Parties' Arguments

Respondent argues that Petitioner has not demonstrated by preponderant evidence that she experienced residual effects of her SIRVA for more than six months. Respondent's Rule 4(c) Report and Motion to Dismiss, filed July 12, 2023, at *9 (ECF No. 33) ("Mot."). Respondent acknowledges that Petitioner sought care several times in the first three and a half months after vaccination, but notes that this was followed by an eight-month gap in treatment between January and September 2020. Mot. at *9-10. At her January 2020 appointment, her orthopedist recommended PT and an MRI – which Petitioner did not do. *Id*. at *10. And during the eight-month gap in care, Petitioner did seek medical treatment for another condition, chronic migraines. *Id*.

Although Petitioner returned for further shoulder treatment in September 2020, Respondent argues that she has not established that those symptoms are related to her mild bursitis from eight months earlier. Mot. at *10. In November 2019, Petitioner had a largely normal shoulder examination with mild symptoms, but when she returned to care after the gap her pain was so severe that she was given prescription pain medication, and had worsened examination findings. *Id*. at *10-11. Additionally, her diagnosis changed from bursitis in November 2019 to rotator cuff tendinosis or tear in September 2020. *Id*. at *11. Respondent emphasizes the speed at which Petitioner's care following the gap proceeded, asserting that after the eight-month treatment gap, Petitioner "sought care at a blistering pace, as she underwent left shoulder surgery just *fourteen days* after her first return visit and *six days* after her appointment with Dr. Miller." *Id*. at *12 (emphasis in original). Respondent does not contest any of the SIRVA QAI, although Respondent's motion does note the examination findings of normal ROM in the early months of Petitioner's treatment.[5]

Petitioner maintains that her symptoms continued for longer than six months, satisfying the statutory severity requirement. Petitioner's Response to Respondent's Motion to Dismiss at *6, filed Oct. 24, 2023 (ECF No. 35) ("Opp."). Although Petitioner paused seeking treatment in January 2020, she provided testimonial evidence explaining that she believed she was unable to seek medical treatment for her shoulder injury without approval from workers' compensation. Opp. at *6. Additionally, she was hesitant to seek

[5] Ultimately Petitioner did have limited ROM and was diagnosed with adhesive capsulitis as a result of surgical findings. Ex. 3 at 7.

in person treatment for a non-life-threatening injury due to the COVID-19 Pandemic. *Id*. When she resumed treatment in September 2020, she reported that her shoulder pain had been present since October 2019 and attributed it to the flu vaccination. *Id*. at *7.

Petitioner argues that despite the treatment gap, there is no evidence that she fully recovered from her injury between January and September 2020. Opp. at *7. And no intervening cause has been identified. *Id*. Petitioner asserts that the SIRVA QAI have been preponderantly satisfied, and she is entitled to compensation. *Id*. at *5-6.

ANALYSIS

V. Statutory Severity Requirement

In order to demonstrate that severity is satisfied, Petitioner must show that she suffered residual effects through late April 2020. Having reviewed the medical records and other evidence, I find no evidence to support Respondent's argument that Petitioner's pause in care starting in January 2020 establishes that her shoulder pain had resolved. On the contrary, the records show that Petitioner received some relief from a cortisone injection in November 2019, but continued thereafter to complain of pain to both her primary care provider and orthopedist. Petitioner's worker's compensation claim was pending during the January to September 2020 treatment gap, and was denied shortly after COVID-19 was declared a pandemic.[6] Thus, the record evidence is consistent with Petitioner's explanation as to why she delayed treatment.

I acknowledge that Petitioner continued to seek medical care for migraines from her neurologist during the treatment gap. This is consistent with Petitioner delaying care for her shoulder due to worker's compensation issues, but somewhat undercuts her explanation that she delayed care due to the COVID-19 Pandemic. As such, I interpret her seeking care for migraines, but not her shoulder pain, during this time to suggest that her shoulder pain was more manageable than migraines – which I acknowledge can be extremely painful – and thus it is relevant to damages. But it does not defeat her claim on severity grounds.

Although Respondent correctly points out that Petitioner's diagnosis changed when she returned to treatment in September 2020, this is explained by the fact that in September, she had a diagnostic ultrasound that allowed her physician to visualize soft tissues and determine that she had a rotator cuff tear. And that she quickly underwent surgery by itself is unremarkable. While this condition is not per se attributable to the

[6] The World Health Organization declared COVID-19 a pandemic on March 11, 2020. Centers for Disease Control Museum COVID-19 Timeline, https://www.cdc.gov/museum/timeline/covid19.html (last visited Sept. 24, 2024).

SIRVA (and treatment for it may not be fully recoverable as damages), it does not preclude the finding that the SIRVA had not resolved at the time it was discovered.

Thus, the evidence preponderantly supports a finding that Petitioner's treatment in September 2020 and thereafter was associated in part with October 2019 vaccine-related injury. Thus, she experienced residual effects of her injury for more than six months, satisfying the statutory severity requirement.

VI. QAI Criteria for Table SIRVA and Other Requirements for Entitlement

Respondent's Rule 4(c) Report and Motion to Dismiss purported to "reserve analysis of petitioner's Table claim and any potential future Causation-in-Fact claim" until Petitioner cured the alleged statutory severity defect. Mot. at 13 n.7. However, Vaccine Rule 4(c) requires that Respondent's Report set forth "a full and complete statement of its position as to why an award should or should not be granted," and states that it "must contain respondent's medical analysis of petitioner's claims and must present any legal arguments that respondent may have in opposition to the petition."

Thus, the Vaccine Rules do not contemplate Respondent raising piecemeal objections to compensation, reserving additional issues for later.[7] Instead, Respondent's report should have set forth his medical analysis and a full and complete statement of his position and any arguments he wished to raise in opposition to the petition. I will afford Respondent the chance to show cause why I should not find that the SIRVA QAI criteria and other requirements for entitlement are satisfied and enter a ruling on entitlement in Petitioner's favor.

Conclusion

Based on my review of the record as a whole, I find that the statutory severity requirement is satisfied by preponderant evidence. Therefore, Respondent's motion to dismiss is **DENIED**.

[7] Only if Respondent noted some preliminary, almost-jurisdictional objection to a claim – for example, whether the claim involved a covered vaccine – might proper circumstances exist to defer addressing the claim's merits (although in such circumstances Respondent would be better served simply by filing a motion to dismiss on those narrow grounds alone).

Respondent is hereby ORDERED to Show Cause by Thursday, October 24, 2024 why a ruling on entitlement in Petitioner's favor should not be issued.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master